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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,633	04/09/2004	Zia Yassinzadeh	021872-001900US	9024

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EXAMINER	
DANG, PHONG SON H	
ART UNIT	**PAPER NUMBER**
3773	
MAIL DATE	**DELIVERY MODE**
11/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,633	YASSINZADEH, ZIA	
	Examiner	Art Unit	
	SON DANG	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-11,14 and 17-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-11,14 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09/13/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 06/30/2009 has been entered. Claims 2, 6, 12-13, 15-16 and 22-67 have been cancelled. Claims 1, 3-5, 7-11 14 and 17-21 are pending in the application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 5, 8, 10-11 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Zucker (U.S Patent No. 2003/0055454). Zucker discloses the invention as claimed including a method for hemostasis of a puncture site (see Fig. 3A-3L) in a wall of a blood vessel at an end of a tissue tract having a sheath (304, Fig. 3A) therein, the method including providing a locating member (ref. 128) having an expansible member (ref. 124) on its distal end, inserting the locating member (Fig. 3B) through the sheath (ref. 304) to within a vessel, expanding the expansible member and drawing the locating member proximally (Fig. 3C-3F), removing the sheath from the tissue tract (Fig. 3G) while the inserted locating member (128, Fig. 3G) remains in place, providing a tubular compression member (ref. 102) having a proximal end, a distal end, a central passage between said proximal end and said distal end, and an expansible tissue compression element (ref. 150) disposed over the distal portion thereof, and advancing the tubular compression member over the inserted locating member (see ref. 102 over

ref. 128, advancing distally so that the expansible tissue compression element 150 is more precise just proximal of the puncture vessel) after the sheath (304, Fig. 3G) has been removed from the tissue tract so that the locating member (128, Fig. 3B) is received in the central passage of the tubular compression member (102, Fig. 3B) and the expansible tissue compression element (150, Fig. 3G) is located within the tissue tract at a predetermined distance (the medial portion of the balloon 150 and the exterior of the blood vessel define a predetermined space where 360 is, Fig. 3J) proximal form the wall of the blood vessel to define a tissue compression region; and expanding the expansible tissue compression element (150, Fig. 3G) within the tissue tract above the blood vessel wall to apply pressure against subcutaneous tissue and to compress said tissue over the puncture site in the blood vessel (the balloon 150 is compressing over the predetermined space which the hemostasis material is occupied over region 360, Fig. 3J) to promote hemostasis, wherein the expansible tissue compression element (150, Fig. 3G) on the compression member (102, Fig. 3G) is left in place until hemostasis has been achieved., the expansible element being a balloon (ref. 150), inflating a distal face of the balloon at an angle to the compression member, unfolding concentric folds of the balloon (see the folds of ref. 150 from Fig. 3F to Fig. 3G), inflating the balloon to a deployed configuration having a concave distal end, and contracting and withdrawing the locating member while the compression member remains in place (Fig. 31-1-31).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 3-4, 7, 9, 14 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucker. Zucker do not disclose the predetermined distance is in a range from about 0.05 inch to about 0.5 inch or 0.2 inch to about 0.3 inch, expanding the balloon to a conical configuration, the distal end of the balloon having a concave distal end, the expansible member deployed diameter, imaging the element during positioning, delivering energy to the puncture site, delivering a clot promoting agent or an anti-infection agent to the puncture site, or instructions on how to use the device. It would have been an obvious design choice to have modified the balloon of Zucker to have a conical shape and to have a distal concave end. Both of these design alterations are well-known in the art and would, therefore, be obvious to modify the balloon of Zucker to meet the design limitations. It would also be obvious to modify the predetermined depth of the expandable balloon in the tissue tract as well as to modify the expansible member's diameter in order to fit the correct size puncture and provide enough pressure to cause hemostasis to occur. It is well-known in the art to image an insertion area in order to determine the exact location of where the device is moving through the tissue. It is also well-known in the art to use some form of energy for either imaging purposes or to seal the puncture site. It is further well-known in the art to use

both clot promoting agents and anti-infection agents to help seal a wound/puncture in a vessel. It would be obvious to provide instructions on how to use the device of Zucker in order to allow a user to properly insert it and use it within and around a vessel.

Response to Arguments

6. Applicant's arguments filed 06/30/2009 have been fully considered but they are not persuasive. The applicant argued on page 5 of the Remarks that Zucker do not disclosed "located within the tissue tract at a predetermined distance proximal from the wall of the blood vessel" and "the balloon 150 directly against the exterior of the blood vessel wall, not spaced by predetermined distance from the wall". This is not persuasive as explained in the above 35 USC 102 rejection that Zucker indeed disclosed a "predetermined space" in Fig. 3J where the hemostasis material is occupied in the region 360. Region 360 is the "predetermined space" where the medial part of the balloon 150 is compressed over the hemostasis material over the exterior of the blood vessel.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SON DANG whose telephone number is (571)270-5809. The examiner can normally be reached on Monday-Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SD

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773